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**FOR CLASS 1 POTENCY<sup>1</sup>**  
**DIPROLENE<sup>®</sup>**  
brand of betamethasone dipropionate  
Ointment, USP, 0.05%  
**IN ACTIBASE<sup>™</sup>**

(potency expressed as betamethasone)

**For Dermatologic Use Only — Not for Ophthalmic Use**

**Summary of Prescribing Information:**

**INDICATIONS AND USAGE** DIPROLENE Ointment is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

**CONTRAINDICATIONS** DIPROLENE Ointment is contraindicated in patients who are hypersensitive to betamethasone dipropionate, to other corticosteroids, or to any ingredient in this preparation.

**PRECAUTIONS** **General** Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. [See **DOSAGE AND ADMINISTRATION** section.]

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. [See **PRECAUTIONS — Pediatric Use.**] If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility** Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topically applied corticosteroids.

Studies to determine mutagenicity with prednisolone have revealed negative results.

**Pregnancy Category C** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies of the teratogenic effects of topically applied corticosteroids in pregnant women. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

**Nursing Mothers** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

**Pediatric Use** Use of DIPROLENE Ointment in children under 12 years is not recommended.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

**ADVERSE REACTIONS** The local adverse reactions that were reported with DIPROLENE Ointment during clinical studies are as follows: folliculitis, 2 per 500 patients; erythema, 2 per 500 patients; pruritus, 1 per 500 patients; vesiculation, 1 per 500 patients.

The following local adverse reactions are reported infrequently when topical corticosteroids are used as recommended. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, milaria.

**OVERDOSAGE** Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. [See **PRECAUTIONS.**]

**DOSAGE AND ADMINISTRATION** Apply a thin film of DIPROLENE Ointment to the affected skin areas twice daily, once in the morning and once at night. Amounts greater than 45 g per week should not be used.

**DIPROLENE Ointment is not to be used with occlusive dressings.**

**HOW SUPPLIED** DIPROLENE Ointment 0.05% is supplied in 15- (NDC 0085-0575-02), and 45-gram (NDC 0085-0575-03) tubes; boxes of one.

Store between 2° and 30° C (36° and 86°F).

For more complete details, consult package insert or Schering literature available from your Schering Representative or Professional Services Department, Schering Corporation, Kenilworth, New Jersey 07033.

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Rev 8/84

**Reference** 1. Cornett RC, Stoughton RB: Topical corticosteroids, in Roenigk H, Maibach H (eds): *Psoriasis*. New York, Marcel Dekker, 1985, pp 337-362.

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DL-A132/13432902

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# In Acne **Cleocin T**<sup>®</sup> Topical Solution (clindamycin phosphate)

## It can make a difference

**Cleocin T**<sup>®</sup> Topical Solution  
(clindamycin phosphate)

**INDICATIONS:** CLEOCIN T Topical Solution is indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea, and pseudomembranous colitis, the physician should consider whether other agents are more appropriate (see CONTRAINDICATIONS, WARNINGS, and ADVERSE REACTIONS).

**CONTRAINDICATIONS:** CLEOCIN T is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincocycline, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

**WARNINGS:** Orally and parenterally administered clindamycin has been associated with severe colitis which may end fatally. Use of the topical formulation results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. Symptoms can occur after a few days, weeks or months following initiation of clindamycin therapy. They have also been observed to begin up to several weeks after cessation of therapy with clindamycin. Studies indicate a toxin(s) produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis.

When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered in cases of severe diarrhea.

Antiperistaltic agents such as opiates and Lomotil may prolong and/or worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dosage is 500 mg.

Mild cases of colitis may respond to discontinuance of clindamycin. Moderate to severe cases should be managed promptly with fluid, electrolyte, and protein supplementation as indicated. Cholestyramine and colestipol resins have been shown to bind the toxin in vitro. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug. Systemic corticoids and corticoid retention enemas may help. Other causes of colitis should also be considered.

**PRECAUTIONS:** CLEOCIN T contains an alcohol base which will cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), bathe with copious amounts of cool tap water. The solution tastes unpleasant.

CLEOCIN T should be prescribed with caution in atopic individuals.

**Pregnancy:** This drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** Nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

**ADVERSE REACTIONS:** Skin dryness is the most common adverse reaction. Clindamycin has been associated with severe colitis which may end fatally (see WARNINGS).

Cases of diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported in patients treated with topical clindamycin.

Other effects which have been reported in association with topical formulations include:

Abdominal pain	Gram-negative folliculitis	Sensitization
Contact dermatitis	Irritation	Stinging of the eye
Gastrointestinal disturbances	Oily skin	

**DOSAGE AND ADMINISTRATION:** Apply a thin film of CLEOCIN T Topical Solution twice daily to affected area.

**HOW SUPPLIED:** CLEOCIN T Topical Solution containing clindamycin phosphate equivalent to 10 mg clindamycin per milliliter is available in the following sizes:

30 ml applicator bottle	NDC 0009-3116-01
60 ml applicator bottle	NDC 0009-3116-02
16 oz (473 ml) bottle	NDC 0009-3116-04

The applicator is designed so that the solution may be applied directly to the involved skin.

**Caution:** Federal law prohibits dispensing without prescription.

B-2-S

For additional product information, see package insert or consult your Upjohn representative.

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**Upjohn**

The Upjohn Company  
Kalamazoo, Michigan 49001

January 1985  
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